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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,936	12/19/2005	Peter Moeller-Jensen	P70330US0	4770
69289	7590	11/19/2009		
COLOPLAST A/S Attention: Corporate Patents Holtedam 1 DK-3050 Humleback, DENMARK			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
			NOTIFICATION DATE 11/19/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/520,936	<b>Applicant(s)</b> MOELLER-JENSEN ET AL.	
	<b>Examiner</b> LAURA C. SCHELL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,6-13,15-17,23,25,26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13,15-17 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 3,6,23,25,26 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “back-flow valve” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 6 and consequently all dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 3 reads “at least one back-flow valve configured to enable a one-way flow of liquid from the control unit to the probe that is characterized by denying a flow of the liquid from the probe to the control unit”. The amendment to claim 6 similarly reads “at least one back-flow valve configured to continuously prevent a flow of liquid from the probe to the control unit”.

Applicant's support for the back-flow valve, however, is found in paragraph [0046] of the published application, and the paragraph provides support for “one or more back-flow valves into the system in order to ensure that irrigating liquid or contents of the bowels do not flow backwards in the irrigating liquid conducting tube or tubes”. The specification does not provide support for the exact and relative placement of the back-flow valve in relation to the other components. For example, the paragraph in Applicant's specification, while providing support for a back-flow valve preventing irrigating liquid or contents of the bowel from flowing backwards in the irrigating liquid

Art Unit: 3767

conducting tubes, it does not provide support for placing the back-flow valve between the control unit and the probe. Furthermore, the back-flow valve is not pictured within the drawings, so placement of the valve also can not be confirmed via the drawings.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Massalsky (DE585360). Massalsky discloses an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit for conducting the irrigating liquid from the reservoir to the probe (the conduit is being interpreted as being comprised of portions g/l and p/n), a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r, through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced by the arrows at the ends of p and n, and the fluid in n is then introduced to g where it is

Art Unit: 3767

directed by k) and a control unit (h) which may be set in at least a cuff inflating position and a liquid transferring position (Fig. 1 discloses that knob s may be set in two different positions), said pump (u) being directly connected to the control unit (directly connected to h via t), said conduit including a first part connecting the control unit with the probe (first part is g which connects h with the probe), and comprising at least one back-flow valve configured to enable a one-way flow of liquid from the control unit to the probe that is characterized by denying a flow of the liquid from the probe to the control unit (Fig. 3 discloses that in channels "v" and "rv" there are back-flow valves with a ball that is seated against a valve seat to prevent fluid from flowing backwards from g back through to m/n) and a second part connecting the reservoir with the control unit (second part p/n connect the reservoir with the control unit h), each of said first and second parts including a gas conducting tube and an irrigating liquid conducting tube (first part has two separate tubes g and l and the second part has the two separate tubes p and n).

In reference to claim 25, Massalsky discloses three flexible tubes connected to a pumping element at one end (tubes g, p and n are all connected to h which is part of the pumping element), the first tube being connected to a gas outlet (gas pumped by u/h exits through p so p is therefore connected to some sort of gas outlet), the second tube being connected to the reservoir (n appears to be connected to the reservoir) and the third tube being connected to the inflatable cuff (g is connected to the inflatable cuff via passageway i in Fig. 4).

In reference to claim 28, Massalsky discloses that the tubes are individually compressed to prevent fluid flow there through such that one of the tubes allows fluid to

Art Unit: 3767

flow there through at the same time that another of the tubes prevents fluid flow there through (Figs. 1-4).

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Massalsky (DE585360). Massalsky discloses an irrigation system (Figs. 1-4) comprising a reservoir (reservoir would be attached to tubes p and n) for irrigating liquid, a probe (b) for arrangement in a user, a conduit (n) for conducting the irrigating liquid from the reservoir to the probe, a fixation member (d) including an inflatable cuff for fixation of the probe in the user, a pump (the pump is being interpreted as including portions u, t, r, s and h as these all appear to be what conducts the pump pressure to the different conduits) for pumping gas into the reservoir to transfer the irrigating liquid from the reservoir to the probe (it appears that air is pumped by u through t into r, through h and down through conduit p which displaces the irrigating fluid up through n, as evidenced by the arrows at the ends of p and n, and the fluid in n is then introduced to g where it is directed by controller k) and a control unit (k) which may be set in at least three different positions including an inactive position (Fig. 4 discloses the cuff inflating position, however if the control unit were turned to an intermediate position such that all the channels were blocked, such as if the knob x in Fig. 4 were rotated 45 degrees either clockwise or counterclockwise, the control unit could be interpreted as being in an inactive position as all the flow channels would be blocked), a cuff inflating position in which gas is pumped into the inflatable cuff (when fluid flows through conduit i) and a

Art Unit: 3767

liquid transferring position in which gas is pumped into the reservoir and irrigating liquid is transferred from the reservoir to the probe (when fluid flows through g to the probe b), wherein the system comprises at least one back-flow valve configured to continuously prevent a flow of liquid from the probe to the control unit (Fig. 3 discloses that in channels "v" and "rv" there are back-flow valves with a ball that is seated against a valve seat to prevent fluid from flowing backwards from g back through to m/n).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massalsky (DE585360). Massalsky discloses the device substantially as claimed except for the pump being powered by an external device or that the device is



Art Unit: 3767

automatically activated. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the pump of Massalsky such that the pump was automatic and the device is automatically activated, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

In reference to claim 26, Massalsky discloses that the device substantially as claimed except for the external device powering said pump being electrically or pneumatically operated. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the pump of Massalsky such that the pump was electrically powered/operated, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. In re Venner, 120 USPQ 192.

### ***Allowable Subject Matter***

Claims 7-13, 15-17, 29-31 are allowed. The allowability of claims 3, 6, 23, 25, 26 and 28 is withdrawn after reviewing the claims and determining that the Massalsky reference should be applied as prior art.

The following is a statement of reasons for the indication of allowable subject matter: Independent claim 7 as well as dependent claims 8-12 are allowed because the subject matter that could not be found is a control unit comprised of a first disc, second disc and intermediate disc, the intermediate disc being rotatable with respect to the first

Art Unit: 3767

and second discs, the rotation setting the cuff inflating and liquid transferring positions, in combination with the other elements of the claims.

Independent claim 13 as well as dependent claims 15-17 are allowed because the subject matter of dependent claim 14, which was not found, was added to independent claim 13, in combination with the other elements of the claims.

Independent claim 29 and dependent claims 30 and 31 are allowed because the subject matter that could not be found is the arrangement of the five canals within the cylindrical element and the arrangement of the five canals in relation to each other, in combination with the other elements of the claims.

### ***Response to Arguments***

Applicant's arguments with respect to claims 3, 6, 23, 25 and 26 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 3767

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/520,936

Page 11

Art Unit: 3767

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767